Perma Pure
Breathe Easier. Be Healthier.

Date Issued: 09FEB2022

DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer, Perma Pure, LLC, in compliance with Article 19 of EU MDR 2017/745. Perma Pure, LLC hereby declares that the medical device and product code listing specified below meets the provision of Annex IV of regulation EU MDR 2017/745 for medical devices.

Manufacturer's Name:	Perma Pure LLC
Business Address:	1001 New Hampshire Ave., Lakewood, New Jersey 08701, USA
SRN #:	US-MF-000003962
Medical Device Name:	Nafion Tube Dryer, Model ME
Models:	ME-050 (0.0366 – 0.0416 diameter), ME-060 (0.0438 – 0.0528 diameter), ME-070 (0.0488 – 0.0588 diameter), ME-110 (0.0698 – 0.0848 diameter)
Device Risk Classification:	EU Class I, Non-sterile, Non-measuring in accordance with Annex VIII of EU MDR 2017/745
GMDN Code and Term:	GMDN 45566 – Gas Sampling/Monitoring Respiratory Tubing, Single-Use
Conformity Assessment Route:	Annex IX, Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation
EU Authorized Representative:	Emergo Europe B.V. Prinsessegracht 20, 2514 AP The Hague, The Netherlands
List of Standards:	EN ISO 10993-1-2020 EN ISO 14971:2012 ISO 14971:2019 EN ISO 13485:2016 ISO 13485:2016

Sidra M. Hankins

Digitally signed by Sidra M. Hankins
DN: cn=Sidra M. Hankins, o=Perma Pure, LLC, ou=VP of QARA, email=shankins@permapure.com, c=US
Date: 2022.02.09 10:52:44 -05'00'

Sidra Hankins
VP, Quality/Regulatory